AWARD NUMBER: W81XWH-09-2-0135

TITLE: Motivating Treatment Seeking and Behavior Change by Untreated Military Personnel Abusing Alcohol or Drugs

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REPORT DATE: September 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

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REPORT DOCUMENTATION PAGE

Form Approved

OMB No. 0704-0188

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INTRODUCTION:

This study will develop and test a brief telephone-delivered motivational enhancement intervention (MET) for substance abusing military personnel who are not currently in substance abuse treatment. The intervention is designed to prompt: (a) a willingness to participate voluntarily in a self-appraisal of substance abuse behavior and consequences, (b) self-initiated change or enrollment in a treatment or self-help program, and (c) cessation of abuse of alcohol or other drugs. Following focus groups with 30 participants, this study will recruit 240 military personnel who have a current substance use disorder via local publicity. The recruitment period will extend over a period of 36 months. Following screening and a baseline assessment, enrolled participants will be randomly assigned to one of two study conditions, each consisting of one 30-60 minute session by phone: (1) the experimental MET condition, or (2) a brief educational session. The MET session will involve a counselor using motivational interviewing strategies to establish an empathic relationship, to support the caller in candidly exploring the problems he/she has experienced with alcohol/drugs, and weigh the pros and cons of future options. The educational session will be didactic and provide information on alcohol and drugs. Participants in both conditions will be reassessed at three and six months following exposure to the intervention. Participation in the trial will be over the duration of 7 months for each participant.

BODY:

The aims of the study are to: (1) manualize participant recruitment mechanisms (e.g., newspaper and radio advertisements, public service announcements, news releases, culturally-specific publicity mechanisms for events, flyers and brochures to be disseminated to human services agencies); (2) develop a motivational enhancement intervention for delivery by telephone to military personnel who are engaging in substance abuse and are not in treatment; (3) evaluate its efficacy in promoting treatment seeking and engagement, and (4) assess its impact on alcohol and drug use outcomes. This yearly report covers the third year of the study (9/1/11-8/31/12) which focused on aim 3, conducting the efficacy trial.

Study Team Formation: Year 1 included the initial steps of hiring and forming a collaborative study team. A system for meeting with study investigators on 3 occasions per month was established. Project goals and goals specific to Year 1 activities were outlined and progressively worked toward throughout the year. Roles and responsibilities of team members were established. Relationships were formed with our collaborators at Joint Base Lewis-McChord and meetings were held monthly. Collaborators at Joint Base Lewis-McChord actively advise and educate our team regarding services available to army personnel, the cultural competence of our study materials, recruitment processes, and assist with recruitment of focus group participants and obtaining meetings with key figures on post. A Project Coordinator was hired and trained. In August of 2010, our counselors and research assistants were hired and training began accordingly.

Over Year 2, we experienced significant staff turnover. However, we were able to rehire and train personnel in positions that were vacated so that Year 2 ended completely staffed. In August of 2011, a full-time Recruitment Coordinator was also hired.

No significant staffing changes were made in Year 3. However, the study's Recruitment Coordinator is leaving the project this fall to pursue graduate studies. A replacement has been hired and began work late August 2012. The new Recruitment Coordinator is a military spouse who is stationed at JBLM and will therefore provide a new and unique perspective to the team.

Human Subjects Protection Review: In Year 1 the study team submitted human subjects protection applications for two phases of the research: pre-trial activities that included procedures for recruiting and conducting focus groups, and all activities associated with the controlled trial. Human subjects protection reviews were conducted by the University of Washington (UW) Institutional Review Board (IRB) and the U.S. Army Human Research Protection Office (HRPO). IRB and HRPO approvals were obtained prior to the initiation of pre-trial activities. An application was submitted to the UW IRB and approved on June 11, 2010 for main-trial activities. The approved

application was then submitted to HRPO. Minor modifications were requested by HRPO and those were addressed and submitted to the UW IRB and HRPO and approved by UW and HRPO on September 15, 2010 and September 17, 2010, respectively. An application for a Certificate of Confidentiality (for the controlled trial) was submitted to the National Institute on Drug Abuse and approved on August 21, 2010 and was granted. All investigators completed the required Collaborative Institutional Training Initiative IRB training course.

No significant modifications to the IRB application have taken place, nor have any adverse events been reported to the board in Years 2 and 3.

Manualize Participant Recruitment Mechanisms: In Year 1, print advertisements for the study were developed. These include advertisements to be placed in newspapers, pamphlets to be included in orientation packets for troops returning from deployment and for soldiers who are new to Joint Base Lewis-McChord, banners and posters to be placed on post, flyers for distribution to post locations (such as service agencies, health clinics, movie theaters, barracks, etc.), and advertisements on media screens throughout post. We have also collaborated with the Army Substance Abuse Program's prevention services to have our publicity materials included and introduced in alcohol and drug education classes. Several discussions with our colleagues at Joint Base Lewis-McChord have generated numerous employable ideas for recruitment with regard to on post advertisement placement.

In Year 2, additional print advertisements were developed that specifically targeted women, prescription drug abuse, and people of color. Other recruitment materials such as pamphlets and brochures were further refined. Print advertisements were placed throughout post. Locations included recreation centers; fitness centers and gyms; restaurants; community and training centers; medical, behavioral health and dental facilities; childcare centers; barracks; unit buildings; and social service agencies. Posters and brochures were also placed at a YMCA and restaurant off-post that have frequent active-duty patrons. Study advertisements were also published in two off-post

newspapers that are distributed on and near Joint Base Lewis-McChord. Ads also ran on LCD screens throughout post and a large recruitment banner rotated between access gates. A webpage was created to provide more information to potential participants. Facebook ads were created and employed.

In addition to visual media, Year 2 also focused on in-person recruitment. Study staff have briefed service providers (unit representatives, chaplains and suicide prevention leaders) on the study so that they may refer soldiers. Staff also distributed recruitment materials at two on-post events, a suicide prevention walk and an annual safety fair. Lastly, on-post collaborators are informing soldiers at reintegration briefings and demobilization briefings of the study.

All recruitment methods initiated in Years 1 and 2 were continued in Year 3. Feedback from soldiers and on-post service providers continues to inform the creation of new and reimagining of older print advertisements. New ads were developed to target families and military spouses. Some standard wording on the ads was also changed to reflect suggestions made by Soldiers. Ad space was purchased in Focus Magazine, an MWR publication widely distributed on base, for the majority of Year 3. Additionally, we created a 15-second ad which has been running during previews at a large movie theatre adjacent to JBLM. Local media venues requested interviews regarding the study. One television and two radio interviews/news stories were aired. Staff have also begun regularly recruiting in-person at an informational booth at Waller Hall, the base's in-processing center.

<u>Focus Groups</u>: In Year 1, separate focus groups were conducted with 10 military personnel who use substances, 7 military personnel who have completed or are currently engaged in substance abuse treatment, and 9 Joint Base Lewis-McChord service providers. Focus group participants were recruited to provide feedback on recruitment advertisements and intervention materials and provided ideas for advertisement placement. Findings from the focus groups were analyzed and used to edit the recruitment materials and to form an advertisement plan.

Develop and Manualize MET Intervention for Target Population: In Year 1, counseling protocols were drafted for the MET and Education conditions. A personalized feedback report tailored to military personnel was developed. Feedback on the personalized feedback report was received and incorporated from the focus groups (described above) and our colleagues at Joint Base Lewis-McChord. Manuals for the Education and MET interventions were developed as well. A counselor training protocol was created. Counselors were hired and began training in August of 2010.

In Year 2, the Education condition was amended to include information about two new substances: Methylenedioxypyrovalerone (MDPV), commonly known as "bath salts"; and synthetic marijuana, commonly known as "Spice" or "K2." Soldiers' abuse of these substances has been a growing concern among Joint Base Lewis-McChord service providers and was therefore included in the intervention. No changes were made to the intervention in Year 3.

Conduct a Randomized Clinical Trial: Protocols for screening and assessment were developed in Year 1. Research assessment staff were hired and trained. In Year 2, Web-based follow-up assessments were created for participants who are unable to complete questionnaires by phone. Recruitment for the study began in late October 2010. As of August 20th 2012, 466 individuals have called the study, 270 have completed the eligibility screen. Of those, 179 were eligible and 139 have enrolled. 108 participants have completed their clinical session, 104 (83%) completed the 3-month follow-up and 74 (76%) completed the final 6-month follow-up. As Table 1 illustrates, demographic characteristics of the study sample are representative of the general Army population.

The counselor and clinical director meet weekly for clinical supervision. Clinical sessions are listened to by the clinical director or PI and feedback is provided to avoid counselor drift. Research staff also meet weekly to discuss project progress and needs. Recordings of assessments are listened to regularly by supervisors and feedback is provided to maintain a high level of quality.

Other

In Year 2, a talk entitled "Overcoming barriers to reaching untreated army personnel with a substance use disorder: Concepts underlying a controlled trial of a motivational enhancement intervention ("Warrior Check-Up")" was delivered at the annual conference for the Society for the Study of Social Problems in Las Vegas, Nevada in August of 2011. The talk was a part of a special session focusing on military populations and substance abuse.

Earlier in the year, we were invited to present our work to General Peter Chiarelli when he visited the University of Washington campus in May 2011. He appeared very interested in the study and was optimistic about its ability to reach and help Army personnel. At his request, we were in discussions with ASAP personnel at Fort Campbell to see if the personnel and Command on that post are interested in having the study publicized there. However, it was determined in Year 3 that without additional funding, it would not be possible to expand the study to Fort Campbell.

In Year 3, two proposals were accepted for presentation at the annual conference of the International Society for Traumatic Stress Studies. One, *Motivating Treatment Engagement Among Active Duty Army Personnel with Co-Morbid Substance Abuse Disorder and Post Traumatic Stress Disorder: Applications from the Warrior Check-Up,* will be part of a symposium focused on the treatment of co-occurring PTSD and substance use disorder in OIF/OEF Veterans. The second is a poster presentation (*Reaching Soldiers with Untreated Comorbid PTSD and Substance Use Disorder: Lessons Learned from the Warrior Check-Up Study*) describing the project's marketing efforts. Additionally, study investigators were invited to submit a manuscript describing the marketing efforts of the Warrior Check-Up to a peer reviewed special issue of the journal Substance Use and Misuse.

KEY RESEARCH ACCOMPLISHMENTS:

Pre-trial activities approved by UW and HRPO IRBs

· Focus groups completed

· Recruitment advertisements developed

MET intervention developed

Education intervention developed

Main trial activities approved by UW and HRPO IRBs

· Certificate of Confidentiality obtained for main trial

· Efficacy Trial was initiated

· Participant recruitment and retention is on target

REPORTABLE OUTCOMES: N/A

CONCLUSION: The past year's activities have focused on maintaining recruitment

levels, implementing the efficacy trial, and beginning dissemination of preliminary

findings and study concepts. The study is meeting its recruitment and retention goals

with no foreseeable obstacles to meeting targets in the proposed timeframe.

Preliminary dissemination efforts have been well received by the public and fellow

researchers.

REFERENCES: N/A

APPENDICES: Table 1: Sample descriptors compared to general Army population,

as of Week 95 (8/20/12)

SUPPORTING DATA: N/A

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Table 1: Sample descriptors compared to general Army population, as of Week 95 (8/20/12)

					Total Army
<u>-</u>	Screened		Enrolled		Population*
Gender	N	%	N	%	%
Female	25	9%	14	10%	13%
Male	245	91%	125	90%	87%
	270		139		
Race					
Native American	2	<1%	1	<1%	<1%
Asian	5	2%	3	2%	4%
African American	42	16%	22	16%	20%
NHOPI	10	4%	7	5%	N/A**
Caucasian	163	60%	81	58%	70%
Other	46	17%	24	17%	6%
Refused	3	1%	1	<1%	N/A**
Age					
18-25	128	46%	65	47%	41%
26-30	76	29%	37	27%	23%
31-35	30	11%	15	11%	14%
36-40	20	8%	12	9%	12%
41+	17	7%	10	7%	10%

^{*}Department of Defense. (2011). *Demographics 2010: Profile of the military community*. Retrieved from www.militaryhomefront.dod.mil/reports

^{**} Army does not assess Native Hawaiian or Pacific Islander or "refused" as race categories